DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

Veinnovations, LLC
C/O Ms. Rosina Robinson, RN, MEd, RAC
Senior Staff Consultant, Regulatory Services
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K050474
Trade/Device Name: Veinnovations, LLC, Veinnovations Infiltration System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, KGZ
Dated: February 22,2005
Received: February 24,2005

Dear Ms. Robinson:

This letter corrects our substantially equivalent letter of April 14,2005 regarding the mailing address.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiehlin, Ph.D.

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050474

Device Name: Veinnovations, LLC, Veinnovations Infiltration System

Indications For Use:

The Veinnovations Infiltration System is an infiltration pump system that is used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional.

Prescription Use X **OR** **Over-The-Counter Use** _____
(21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050474

K050474

APR 1 4 2005

510(k) Summary
Veinnovations, LLC
Veinnovations Infiltration System

1. SPONSOR

Veinnovations, LLC
2210 Dean Street N1
St. Charles, IL 60175
Contact Person: Fred McKinney
Telephone: 630-416-0258

Date Prepared: February 22, 2005

2. Device Name

Proprietary Name:	Veinnovations Infiltration System
Common/Usual Name:	Infiltration pump and disposables
Classification Name:	Infusion pump and accessories

3. PREDICATE DEVICE

HK Surgical, Inc., Klein Surgical Infiltration Pump, Model KIP II - K031432.

4. DEVICE DESCRIPTION

The Veinnovations Infiltration System consists of the Infiltration Pump and proprietary, sterile, single use Veinnovations Y Infiltration Set.

5. INTENDED USE

The Veinnovations Infiltration System is an infiltration pump system that is used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Veinnovations Infiltration System is substantially equivalent to the cited predicate device based on its indications for use, design, materials, and operational characteristics. Veinnovations LLC believes that differences between devices are minor and raise no new issues of safety or effectiveness.